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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

MERLE KOVTUN, Individually and on Behalf of Others Similarly Situated,

Plaintiff,

v.

VIVUS, INC., LELAND F. WILSON, and WESLEY W. DAY, Ph.D.,

Defendants.

Case No. 4:10-CV-04957-PJH

NOTICE OF MOTION AND MOTION TO DISMISS SECOND AMENDED CLASS ACTION COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: April 18, 2012
Time: 9:00 a.m.
Courtroom: 3 (3rd Floor)

The Honorable Phyllis J. Hamilton

NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT on April 18, 2012, at 9:00 a.m., or as soon thereafter as the matter may be heard by the Court, located at 1301 Clay Street in Oakland, California, in Courtroom 3 before the Honorable Phyllis J. Hamilton, defendants VIVUS, Inc., Leland F. Wilson, and Wesley W. Day, Ph.D. (together "Defendants") will and hereby do move the Court, pursuant to Rules 8(a), 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the provisions of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), for an order dismissing, with prejudice, each and every purported claim for relief asserted in the Second Amended Class Action Complaint for Violation of Federal Securities Laws (the "New Complaint" or "SAC"). Defendants' motion is brought on the grounds that the New Complaint's allegations fail to state a claim upon which relief can be granted and/or are not pled with the particularity required by Rule 9(b) and the PSLRA. Defendants' motion is also based on Plaintiff's failure (a) to comply with the Court's directive, set forth in its Order dated October 13, 2011 (the "10/13 Order"), to specify what (i) portions of Defendants' public statements Plaintiff contends were false and misleading and (ii) facts support an inference that those statements were knowingly false or misleading when made, and (b) to include a "short and plaint statement of the claim" showing that Plaintiff is entitled relief, as contemplated by Rule 8(a)(2). Additionally, some of the statements on which Plaintiff predicates his purported claims are not actionable under the safe harbor provisions of the PSLRA and/or the bespeaks caution doctrine.

Defendants' motion is based on this Notice of Motion and Motion, the Memorandum of Points and Authorities that follows, the accompanying Declaration of Benjamin T. Diggs and Request for Judicial Notice in support thereof, the 10/13 Order, all pleadings and papers filed in this action, oral arguments of counsel at the contemplated hearing on this motion, and any other matters as may come before the Court.

STATEMENT OF ISSUES TO BE DECIDED

CIVIL L.R. 7-4(A)(3)

1. Whether Plaintiff fails to state a claim for relief under Section 10(b) of the Securities Exchange Act of 1934 (Count I) because he fails to allege a material misstatement or omission with the plainness and specificity mandated by applicable law. 15 U.S.C. § 78u-4(b)(1); Fed. R. Civ. P. 8(a)(2), 9(b) & 12(b)(6).

2. Whether Plaintiff fails to state a claim for relief under Section 10(b) of the Securities Exchange Act of 1934 (Count I) because he does not plead specific facts that give rise to a strong, cogent and compelling inference that Defendants acted with scienter. 15 U.S.C. § 78u-4(b)(2); Fed. R. Civ. P. 9(b) & 12(b)(6).

3. Whether Plaintiff's purported claim under Section 10(b) of the Securities Exchange Act of 1934 (Count I) fails to state a claim for relief because the alleged misstatements are rendered inactionable by the PSLRA's "safe harbor" and/or "bespeaks caution" doctrine. 15 U.S.C. § 78u-5(c); Fed. R. Civ. P. 9(b) & 12(b)(6).

4. Whether Plaintiff's purported claim under Section 20(a) of the Securities Exchange Act of 1934 (Count II) fails to state a claim for relief because the Complaint does not adequately allege a primary violation of that Act. 15 U.S.C. § 78t; Fed. R. Civ. P. 9(b) & 12(b)(6).

5. Whether Plaintiff's purported claim under Section 20(b) of the Securities Exchange Act of 1934 (Count III) fails to state a claim for relief because the Complaint does not adequately allege a primary violation of that Act. 15 U.S.C. § 78t; Fed. R. Civ. P. 9(b) & 12(b)(6).

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MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

I. INTRODUCTION

At the October 12, 2011 hearing, when this Court granted Defendants' motion to dismiss Plaintiff's Amended Class Action Complaint (the "Prior Complaint" or "AC") with leave to amend, the Court told Plaintiff: "I view it as your job to tell me what the statement is that you're claiming is false and then tell me what about that statement is false and why…if it's because something has been omitted, what specifically has been omitted from what particular statement." Hearing Tr., Oct. 12, 2011 (Ex. Z), at 19:7-11.[1] Despite the addition of *nearly 100 pages* to his New Complaint, Plaintiff's 182-page tome still fails to meet this basic pleading requirement.

In his Prior Complaint, Plaintiff repeated a list of 11 asserted "reasons" why Defendants' statements about the clinical trial results for and future prospects of VIVUS's developmental weight-loss drug Qnexa were supposedly false or misleading, as if all 11 applied to every statement. With the New Complaint, Plaintiff tries to make it appear that he is breaking things out. After quoting, for example, an entire VIVUS press release, he now detaches individual sentences or phrases and, having grown his list of "reasons" from 11 to 20, asserts that those sentences were false or misleading for between 2 and 12 of those "reasons." But repeating the same falsity assertions over and over again – dozens of times in many cases – neither complies with Rule 8's mandate of a "short and plaint statement of the claim," nor with the Court's 10/13 Order. It does not address the fundamental problem with Plaintiff's allegations, either.

Plaintiff's New Complaint still falls short because his asserted "reasons" do not constitute *facts*. Instead, they are inaccurately summarized, out-of-context comments from some participants in a U.S. Food and Drug Administration ("FDA") Endocrinologic and Metabolic Advisory Committee (the "Advisory Committee") held July 15, 2010, the final day of the alleged class period. In a close vote, that Advisory Committee decided not to recommend Qnexa for

[1] We cite exhibits to the Diggs Declaration as "Ex.__". We request that the Court take judicial notice of these documents because all are either referenced or quoted in the New Complaint or otherwise the proper subject of judicial notice. *See* Request for Judicial Notice, filed concurrently. For the Court's convenience, exhibits referenced in Defendants' previous motion have the same exhibit designations. In these papers, citations to paragraph references ("¶") are to the New Complaint unless otherwise noted. We cite to the memoranda supporting Defendants' previous motion to dismiss (Dkts. 30 & 36) as "Prior Motion" and "Prior Reply," respectively.

FDA approval. But the fact that a Committee member may have asked a question about, say, potential cardiovascular risk, or mentioned that more long-term data on the subject would be useful, does not mean or even suggest that Defendants lied about what the cardiovascular-risk data from the Qnexa trials actually showed. Plaintiff does not allege specific facts from the trial data suggesting that the many adverse outcomes that he hypothesizes were actually observed, at all or to any clinically significant degree. Those facts are not pled because they do not exist.

Plaintiff can assert *27 times*, as he does, that there "was a serious concern" about "the possibility" of increased suicidal ideation, *e.g.*, ¶ 55(d)(iv); but that assertion is of no legal consequence absent, at a minimum, alleged *facts* suggesting that there *was* some increase in suicidal ideation evident from the clinical trial data. Plaintiff can assert *73 times*, as he does, that the Phase 3 trial population was "unbalanced" such that results from the *4500* trial subjects (actually, quite a large trial) could not be generalized to the broader population, *e.g.*, ¶ 55(a)(iii); but the assertion again is of no legal consequence absent at least some alleged *facts* that VIVUS's clinical trial data *was* statistically flawed owing to defects in the trial subject group. From their earliest discussions of the clinical trial data, Defendants reported that Qnexa was effective and its safety profile was consistent with its two long-approved component drugs. Plaintiff simply offers no *facts* to explain why his proffered "reasons" (a) rendered a Defendant's statement false when made or (b) was believed by Defendants at the time to render Qnexa's approval by FDA or commercial success unlikely. Those explanations were missing from the Prior Complaint; they remain absent from the New Complaint; and they mandate dismissal.

Furthermore, the New Complaint does nothing to address the other deficiencies that Defendants noted in their Prior Motion – issues that the Court found unnecessary to reach – as the New Complaint is little more than a reorganized, bulked-up version of his earlier pleading. Plaintiff has made no major changes to his allegations; he still attempts to work backward from the Advisory Committee vote to turn Defendants' accurate characterizations of clinical trial results and expressions of optimism – both tempered at every turn by extensive risk disclosures – into a fraud. As Defendants made clear in the Prior Motion, Plaintiff fails to allege *facts* supporting a plausible conclusion that Defendants' public statements were false or misleading

even against a Rule 8(a) standard, much less under the heightened pleading standards of Rule 9(b) and the PSLRA. Every argument Defendants raised in their motion to dismiss the Prior Complaint remains applicable to the New Complaint. *First*, Plaintiff has not adequately alleged any statement was false and misleading; his efforts to insinuate falsity fail for several reasons.

- Plaintiff's suggestion that some new "truth" about Qnexa only emerged at the July 15, 2010 Advisory Committee meeting still fails to address the FDA's public release of its full analysis of Qnexa two days earlier, and the resulting jump in VIVUS's stock price.
- Plaintiff mischaracterizes the outcome of the Advisory Committee meeting. Instead of undercutting VIVUS's prior public statements, the Committee discussion confirms that VIVUS accurately disclosed safety data that was interpreted in the context of the known safety profiles of Qnexa's component drugs, and that votes against approval reflected a desire to see more long-term data to confirm Qnexa's safety.
- While Committee members may have disagreed about whether the trial data were sufficient to support approval, those differences of opinion do not render false Defendants' prior statements about the trials.
- At worst, Defendants' enthusiasm over what they saw as outstanding results were non-actionable expressions of opinion and optimism and/or forward-looking statements within the PSLRA safe harbor and bespeaks caution doctrines.

Second, even if Plaintiff adequately alleged falsity, his fraud claim fails because he does not allege scienter with anything close to the specificity required. His "Confidential Witness" allegations are substantially unchanged and remain a collection of beside-the-fact recollections from persons alleged to be in no position to know anything meaningful anyway. Plaintiff alleges none of the accepted indicia of scienter. Far from the cogent and compelling portrait of deceit required, Plaintiff's scienter allegations confirm Defendants' conclusions concerning Qnexa's trial results and highlight their sincere belief in Qnexa's and VIVUS's prospects.

Because Plaintiff failed to follow the Court's instructions, and has again failed to plead either falsity or scienter, the New Complaint should be dismissed, without further leave to amend.

II. FACTUAL BACKGROUND

VIVUS is a pharmaceutical company. Its lead product candidate in clinical development is Qnexa, an experimental drug for treating obesity. ¶ 4. Qnexa is a proprietary combination of two medications long approved by the FDA – phentermine (also known under the brand name Adipex-P) and topiramate (also known under the brand name Topamax). ¶ 44. Phentermine was approved in 1959 as a weight-loss drug. Topiramate is an anti-convulsant, approved to treat

epilepsy and migraine headaches. *Id*. Topiramate in particular has a history of dose-limiting side effects, but both drugs have a well-documented safety profile, developed through decades of experience with millions of patients. *Id.*; Ex. D at 2, 170-236. Both drugs' approved dosing levels as monotherapies are higher than the amounts used in any Qnexa formulation. Ex. D at 2.

As discussed in Defendants' Prior Motion, drug candidates like Qnexa must undergo a rigorous, expensive process of clinical testing and trials before a company may seek FDA approval for sale of the drug through a New Drug Application ("NDA"). *See* Prior Mot. Section II.A. The process is intended to ensure that drugs approved for sale are both effective and safe. Ex. A. As part of its process, the FDA may convene an advisory committee of doctors and other scientists to consider whether a drug's health benefits outweigh its known risks, and issue a recommendation to the FDA. *See* 21 CFR §§ 14.160, 14.171. As Plaintiff concedes, the studies, data submissions and analyses required to secure FDA approval are lengthy and very expensive. ¶ 39 (average of 12 years and more than $700 million for new drug approval). The process is also inherently risky. *Id*. (one in 1,000 compounds tested in laboratory ever reach human testing and only 8% of drugs entering Phase I clinical trials eventually receive FDA approval).

A. Statements About Qnexa and the Clinical Trial Results

As the alleged class period began, VIVUS had completed certain Phase III clinical trials ("Phase 3 trials") of Qnexa involving more than 4500 overweight and obese adults. ¶ 43. These trials were randomized, double-blind, placebo-controlled studies, and included two of three Qnexa dose levels: full-, mid- or low-dose. *Id;* Ex. B at 2. Two trials were done under an FDA Special Protocol Assessment ("SPA"), meaning that the trials' design, clinical endpoints and proposed analyses were acceptable for FDA approval. Ex. C at 1, 8; Ex. D at 6. On September 9, 2009, the start of the class period, VIVUS issued a press release announcing key results of its year-long trials: (a) obese patients on the top dose of Qnexa had an average weight loss of 14.7%, with significant improvements in associated co-morbidities; (b) the results exceeded FDA efficacy benchmarks; and (c) Qnexa demonstrated a favorable safety profile. ¶ 54; Ex. B at 1. In December 2009, VIVUS submitted an NDA supported by these results to have Qnexa approved as an obesity drug. ¶ 7. On March 1, 2010, FDA accepted the NDA and agreed to review Qnexa.

Id. Thereafter, FDA evaluated the NDA and convened an Advisory Committee meeting. ¶ 8.

Between release of top-line Phase 3 trial results on September 9, 2009 and the Advisory Committee meeting the following July, VIVUS made various public statements about the trial results and Qnexa's prospects for FDA approval and marketability. ¶¶ 54-203. These statements were made into a securities market that recognized the high risk of drug development, particularly given that, as Plaintiff alleges, "in recent years, the FDA has been raising the bar for new drug approvals," with intense scrutiny of weight-loss drugs. ¶¶ 47-48. VIVUS noted these risks in each public statement, and provided detailed risk disclosures in its periodic SEC filings, including the risks that Qnexa would not be recommended for approval or approved, or that additional and more extensive trials might be required. *E.g.*, Exs. O, P. As Plaintiff acknowledges, market analysts also noted these risks. *E.g.* ¶ 272 (quoting analyst report). VIVUS stock traded in an efficient market that "rapidly absorbed all publicly material information regarding Vivus," and reflected that information, including the disclosed risks, in VIVUS's stock price. *Id.* ¶¶ 34-35.

B. Disclosure of Briefing Documents and Later Committee Meeting and Vote

On July 13, 2010, two days before the Advisory Committee meeting, the FDA publicly released both VIVUS's briefing document and its own analysis of Qnexa's clinical trial data. ¶ 205; *see also* Ex. E. Market watchers (but not VIVUS) reacted by stating that the FDA response was "benign" and "suggests that safety concerns won't stall approval for Qnexa." Ex. F. Following the release, VIVUS's stock price climbed 17% on July 13, 2010, its largest one-day increase since VIVUS released its top-line trial results on September 9, 2009. Ex. H.

The Advisory Committee met publicly on July 15, and heard from both VIVUS and FDA reviewers on Qnexa's safety and efficacy. ¶ 204; Ex. G. VIVUS presented scientists and medical doctors who opined that the studies showed Qnexa to be beneficial and effective, and that observed side effects were consistent with those associated with Qnexa's FDA-approved components and in any event should not preclude approval. *See* Ex. G at 83-92. The FDA did not dispute efficacy. ¶ 207. However, the FDA staff presenter and some Committee members raised questions about long-term safety that these members felt were not ruled out by the data. *Id.* ¶¶ 215-30. By a 10-6 vote, the Committee said that "based on the current available data" it did

not believe that the "overall benefit-risk assessment of Qnexa is favorable to support its approval." *See* ¶ 207; Ex. G at 340. After the vote, VIVUS's stock price fell.

C. Plaintiff's Fraud Allegations

The New Complaint alleges that, between the September 9, 2009 release of top-line Phase 3 trial results and the Advisory Committee vote on July 15, 2010, Defendants made statements about Qnexa's safety and its potential for FDA approval, while understating the associated health risks. *See* ¶¶ 5, 54-203. Plaintiff says the "truth" about Qnexa was revealed only at the Committee meeting (ignoring that FDA released its analysis two days before). ¶¶ 12, 204; *cf.* Ex. G. To support his claim, Plaintiff refers to certain Defendant statements that either accurately described Qnexa clinical trial results or made the point – backed up by VIVUS's NDA filing and its expenditure of resources to support it – that Defendants believed Qnexa was safe and effective.

As to scienter, Plaintiff selectively quotes the most unfavorable statements by Committee members and asserts Defendants "must have" held those same concerns all along (ignoring the contrary views of a sizeable Committee minority). ¶ 249. Plaintiff also questions a stock issuance by VIVUS and stock sales by both Mr. Wilson and non-defendant Guy Marsh that he admits were pursuant to Rule 10b5-1 trading plans adopted six months before the alleged class period. *Id.* ¶¶ 276, 292-96. Plaintiff alleges no stock sales by Dr. Day.

III. LEGAL STANDARD

A. Rule 12(b)(6) of the Federal Rules of Civil Procedure

The Court must dismiss a complaint under Rule 12(b)(6) where it fails to allege facts sufficient to support a cognizable legal claim. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). The Court should not accept "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Nor should a Court accept legal or factual allegations based on unwarranted deductions or unreasonable inferences, or allegations that contradict materials properly subject to judicial notice. *See Clegg v. Cult Awareness Network*, 18 F.3d 752, 754-55 (9th Cir. 1994).

B. Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5

To state a Section 10(b) claim, a plaintiff must allege: (1) a misstatement or omission

(2) of material fact (3) made with scienter (4) on which she relied (5) and which proximately caused plaintiff's injury. *E.g., DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002). The claim must be pled with particularity. Fed. R. Civ. P. 9(b). To satisfy the PSLRA's stringent standards for pleading falsity, a plaintiff must identify (1) each statement alleged to have been misleading, (2) the reasons why it is misleading, and (3) if an allegation regarding the statement or omission is made on information and belief, all facts on which that belief is based. 15 U.S.C. § 78u-4(b)(1). *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 988 (9th Cir. 1999); *see also In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833, 839 (N.D. Cal. 2000). This said, the heightened standard for pleading securities fraud "is not an invitation to disregard the requirement of simplicity, directness, and clarity of Fed R. Civ. P. 8, which requires that a complaint contain 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1239 (N.D. Cal. 1998).

A complaint must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). In the Ninth Circuit, a plaintiff must plead "deliberately reckless or conscious misconduct" by the defendant. *Silicon Graphics*, 183 F.3d at 974. Deliberate recklessness involves, "a highly unreasonable omission, involving … an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Zucco Partners LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009). A complaint can be sustained only "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Courts must consider plausible non-culpable explanations for a defendant's conduct as well as inferences favoring plaintiff. *Id.*

IV. ARGUMENT

A. Plaintiff Did Not Comply with the Court's 10/13 Order to Clearly Specify the Allegedly False Statements or Omissions

In dismissing the Prior Complaint, the Court found that Plaintiff's inclusion, after each

complained-of Defendant statement, of a long, identical list of purported "reasons" the statement was false or misleading, failed to satisfy even threshold pleading standards. *See* Ex. Z at 19; *id.* at 27 ("You can write a complaint that says, 'This is the statement that we allege to be false or misleading. These are the ***facts*** that support… our allegation as to why it's false and misleading.'") (emphasis added). Despite adding dozens of pages of allegations, Plaintiff still has not satisfied this basic requirement, and has not complied with the Court's 10/13 Order.

At most, Plaintiff attempted to comply with one part of the Court's directive. He now follows his lengthy quotations of VIVUS public releases with paragraphs that list the many statements within those releases upon which he purports to base his claims. His New Complaint remains deficient, however, because he still fails to allege *factual information* that supports his assertions that Defendants' statements were false or misleading when made. Instead, he merely repeats the same cut-and-paste job that left his Prior Complaint inscrutable, albeit he now cuts and pastes from a somewhat larger set of excerpted comments from the Advisory Committee materials. His effort to establish a loose subject-matter relationship between the statements and his falsity "reasons" this time around – so that, for example, he trots out the same four "reasons" related to trial discontinuation after any VIVUS statement about Qnexa being well tolerated (*e.g.*, ¶¶ 82-84, 96(a)), the same seven "reasons" after any VIVUS statement related to psychiatric safety (*e.g.*, ¶¶ 57(c)-(e), 59(f)-(i)), the same six "reasons" after any statement related to cardiovascular risks (*e.g.*, ¶¶ 55(a), 76(d)), and so on – does no more than add many more pages. It does not cure the fundamental defect – that he offers no factual support for his conclusory assertions. *See Robertson*, 749 F.2d at 533-34; *Wenger*, 2 F. Supp. 2d at 1239. [2]

[2] Indeed, Plaintiff's efforts to link statements and "reasons" together are largely haphazard and/or nonsensical. Examples are too numerous to list in full, but the first few paragraphs of the New Complaint's "misleading statements" section provide several: *e.g.*, ¶ 55(a) (alleging statement that patients taking Qnexa achieved significant improvements in cardiovascular and metabolic risk factors was misleading because it did not also disclose that Phase 3 trials included many more women than men); ¶ 57(c) (alleging statement that *serious* adverse events were same in drug and placebo was false because it did not mention that *total* adverse events were higher on drug than placebo in certain categories or that a decrease in potassium was noticed during a *Phase 1* trial); ¶ 59(b) (alleging statement that "the majority of adverse events were mild" was misleading because it did not say that "Phase 3 trials also showed other, less common, but significant, potentially serious and life-threatening side effects…" without alleging facts that these "other" alleged events were anything but mild, to the extent they were observed at all).

As Plaintiff notes, the briefing documents that presented the Qnexa Phase 3 trial data, released prior to the Advisory Committee meeting, comprised some 555 pages of data and analysis. ¶¶ 12, 301. If the facts – that is, the hard data gathered over more than a year of clinical trials involving 4500 patients – really supported any of Plaintiff's claims, one would expect these materials to provide a treasure-trove of material for the New Complaint. Instead, Plaintiff all but ignores the data itself, and attempts to buttress his claim almost entirely through selected snippets of the Committee meeting transcript and summary minutes in which some members expressed concerns conditionally – *not* about what the Qnexa trial data actually showed but about whether it covered a sufficient amount of time to rule out *potential* issues. The fact that he has added to his collection of "reasons" – boosting his list from 11 in the Prior Complaint to around 20 – and pasted them in a handful of different patterns in his New Complaint, rather than repeating the complete set after each statement, does not mean he has complied with the Court's directive to clearly present facts supporting his claim that each (or any) statement is false and misleading.

Plaintiff alleges the implausible – that VIVUS spent hundreds of millions of dollars and years developing a drug that it knew would not be approved. He has asserted, both in his New Complaint and at the October 12 hearing, that Qnexa had life-threatening side effects that Defendants supposedly failed to disclose.[3] He should be required to substantiate these grave assertions with something more than a handful of excerpted opinions and observations from Advisory Committee members (often combining several such comments to form a single "reason"). *E.g.* ¶ 55(a)(i) (borrowing words from various comments at Ex. G 189, 316, 320, 323). If anything, the New Complaint is more convoluted than its predecessor, and requires the same code cracking from Defendants and the Court. *Wenger,* 2 F. Supp. 2d at 1244 ("In the context of securities class action complaints, courts have repeatedly lamented plaintiffs' counsels' tendency to place the burden on the reader to sort out the statements and match them with the

[3] At the October 12 hearing, Plaintiff's counsel began his argument with the dramatic assertion that "the FDA advisory board averted one of the worst national medical disasters imaginable." Ex. Z at 8. If there were factual support for that bold assertion, one would expect Plaintiff to have included it the New Complaint. That such facts are absent speaks volumes. Far from being the killer drug Plaintiff tries to portray, there was precisely one death among the very large trial population – an individual who was part of the *placebo arm* of the study. Ex. G at 53.

corresponding adverse facts to solve the 'puzzle' of interpreting plaintiffs' claims."). Because Plaintiff has not complied with the Court's 10/13 Order and his New Complaint again "requires a laborious deconstruction and reconstruction of a great web of scattered, vague, redundant, and often irrelevant allegations," the New Complaint should be dismissed. *Id.* at 1243.

B. Plaintiff Fails to Allege Any False or Misleading Statements

Even if the New Complaint met the basic mandates of Rule 8 and the 10/13 Order, it would still fall far short of stating a claim. The gravamen of securities fraud is a defendant statement that was false or misleading when made. *See Ronconi v. Larkin*, 253 F.3d 423, 437 (9th Cir. 2001). Plaintiff's New Complaint still does not allege one.

1. Plaintiff Fails to Allege Facts Showing That Defendants' Statements About the Safety Results of Qnexa's Trials Were Materially False or Misleading

Plaintiff asserts that VIVUS investors were unaware of Qnexa's alleged health risks and the "inadequacy" of clinical trial data prior to the Advisory Committee's July 15, 2010 meeting. ¶¶ 12, 301. Plaintiff's argument ignores the undisputed fact that the FDA publicly released briefing documents, with extensive trial data and the FDA's analysis of potential safety issues, on *July 13, 2010*, two days *before* the Committee meeting and vote. ¶12 n.2 (citing July 13 article). In response to the 307-page briefing from VIVUS and 248-page FDA analysis memorandum (the "FDA Memo"), VIVUS's stock price went *up* 17% – its largest one-day gain since September 9, 2009, when VIVUS first released Qnexa Phase 3 trial data. *See* Ex. H; *compare In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 462-63 (S.D.N.Y. 2008) (Plaintiff's (unsuccessful) fraud claims based, in part, on stock price *drop* after FDA briefing documents were released before FDA meeting). The market, which Plaintiff alleges to be efficient (*see* ¶¶ 34-35), clearly saw the FDA Memo, including its review of Qnexa's safety data, as positive for Qnexa's approval prospects, as analysts reported. *See, e.g.*, "Vivus Rises on 'Benign' Review of Diet Pill's Safety," Bloomberg BusinessWeek, July 13, 2010; *see also* "Vivus Weight-Loss Pill Works – FDA," TheStreet.com, July 13, 2010 (all safety issues raised by FDA Memo "had been anticipated by investors as major areas of discussion" at the Committee meeting). *See* Exs. F & I.[4]

[4] In response to the market's receipt and positive reaction to the trial data two days before the Committee vote, Plaintiff adds a new allegation: "Nor were investors aware of the FDA Panel's

Plaintiff selects snippets from the FDA Memo and declares them to be "omitted material adverse facts." *Compare, e.g.*, ¶ 55(f), (g) *with* ¶ 205. But this conclusion just ignores the July 13 market reaction. No new data came to light on July 15, and Plaintiff does not allege otherwise. The only "new" thing that day was the Committee's split vote to not recommend approval of Qnexa. *That outcome* – the adverse resolution of a disclosed risk – is what the stock price reacted to on July 15. The fact that some panel members interpreted the data differently or ascribed varying weight to their individual concerns does not render VIVUS's prior statements false. *E.g. AstraZeneca*, 559 F. Supp. 2d at 471; *Nathenson v. Zonagen*, 267 F.3d 400, 420 (5th Cir. 2001).

Looking at the meeting record as a whole, the Committee's debate and the members' difficult voting decisions simply *negate* any inference of fraud. Ex. G at 343-68. Member comments reveal that their chief concern was *not* that the data reflected a poor, previously undisclosed safety profile or that the data contradicted earlier public information. Rather, some felt there simply was not enough data on long-term use of the drug, given that certain side-effects with prior weight-loss drugs arose only after prolonged use. Anticipating long-term use of Qnexa, Dr. Proschan's comments were typical: "I think if we had had longer follow-up, I probably would have voted [for approval]. But I just don't feel comfortable with one year follow-up." *Id.* at 351.[5] But VIVUS did not mislead anyone about the studies it conducted. It accurately disclosed its trial design, including that the clinical trials relied upon in its NDA had (to that point) collected just over one year of results; again Plaintiff does not contend otherwise.

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explanation of that 555 pages of data or its view of what it showed and its quality." ¶ 12. This addition presages Plaintiff's repetition of an argument he made in the last round of motion briefing that investors could not grasp the briefing documents' import until two days later and initially reacted to their "tone" rather than the safety information within. This argument cannot square with Plaintiff's fraud-on-the-market allegations. ¶¶ 34-35; *see* Prior Reply Section II.A.2.a. The argument is also factually incorrect. A Google search of "July 13 2010 VIVUS" shows that investors did not need to dig beyond headlines to see that the documents focused on safety issues. *See, e.g.* "Vivus weight loss drug faces safety questions," Newsday, July 13, 2010 (Ex. AA); "New obesity pill works…but safety concerns loom: FDA," NY Daily News, July 13, 2010 (Ex. BB). The market price reflected the safety data in the briefing documents. Investors, like a substantial minority of the Committee, felt it *supported* VIVUS's optimistic outlook.

[5] *See also, e.g.*, comments of Dr. Burman, Ex. G at 352 ("It is difficult if not impossible to weigh these issues since the clinical studies are only for about a year…."); Dr. Flegal, *id*. at 354 ("I think we need more data."); Dr. Bersot, *id*. at 359 ("We need more evidence in the high-risk cardiovascular disease patient."); Dr. Heckebert, *id*. at 368 ("But I think we do need more information about [teratogenicity] as well as the other serious endpoints that I mentioned.").

That some Committee members wanted to see whether the strong reported safety results persisted with longer use does not mean, or suggest, that VIVUS misreported anything. This is especially true where the applicable FDA Guidance for Industry provided that "weight loss and weight maintenance should be demonstrated over the course of at least 1 year" and that "a reasonable estimation of the safety of a weight-management product upon which to base approval generally can be made … [after] 1 year of treatment." *See* Ex. D at 241, 246. Having completed the contemplated year of trials, VIVUS was justifiably excited about the data collected. After all,

- Qnexa's components were both long-approved medications;
- The design and execution of two Phase 3 trials were under an approved SPA;
- The side effects observed in those trials were consistent with the safety profiles of the component drugs; and
- A longer-term outcomes trial was already under discussion with the FDA.

See Ex. C at 8; Ex. D at 17-18. The Advisory Committee's call for additional tests and more data is, at most, an after-the-fact critique. It cannot buoy a claim that VIVUS's statements were knowingly false or misleading when made. *See, e.g. Padnes v. Scios Nova Inc.*, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996) (disagreements over study design and interpretation insufficient to allege falsity: "[W]here a company accurately reports the findings of a scientific study, it is under no obligation to second-guess the methodology of the study.").

Nor is this a case where a bombshell of previously undisclosed data was dropped late in the game, undercutting prior confident statements. *See Heywood v. Cell Therapeutics, Inc.*, 2006 WL 5701625, at *6 (W.D. Wash. May 4, 2006) (distinguishing cases where "defendants either grossly misrepresented some specific material fact, or failed to disclose some concrete indication that they could not expect FDA approval"). Instead, the fact that experts split about 60-40 on approval after poring over the data and a day-long hearing confirms that this was, at worst, reasonable minds interpreting data differently, *not* active deception. Assessing similar claims against AstraZeneca, that court noted that at the Advisory Committee meeting, the "[sponsor] had its side of the case and the FDA staff had its side." In that context, the vote against approval "does not mean that [the sponsor] was not conscientious in advocating the drug [] before the FDA, nor

does it mean that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated." *AstraZeneca*, 559 F. Supp. 2d at 471.

Nothing suggests that those voting *for* approval failed to appreciate some newly disclosed adverse fact; there was none. These members just came to a different conclusion. Dr. Hendricks' comment as he voted for approval is illustrative: "I think the sponsor did an outstanding job of managing several very difficult clinical trials, and did an outstanding job producing the data, and that the data does show … that the drug is reasonably safe and that we should approve it." Ex. G at 364. Ms. Coffin, also voting in favor, said she was "a little surprised" by the "no" votes, saying, "I do believe that the side effects that were listed here were reasonable … I do feel like we're letting perfect get in the way of possible [by voting against approval]." *Id*. at 365-66.

Even those voting against approval, quoted extensively by Plaintiff, were conflicted. For example, Dr. Cragan commented: "I voted no, and *I also found it a very difficult decision*. This drug is clearly effective and has the potential to change many people's lives. And I really hate to be on record voting against that." *Id*. at 366 (emphasis added). After Dr. Rogawski's "yes" vote, Dr. Morrato voted "no," saying that "many of my reasons are very similar to what [Dr. Rogawski] just shared … I just erred on the no side…." *Id*. at 345. Dr. Burman, to whom the New Complaint attributes the list of potential side effects that Plaintiff says renders nearly every Defendant statement false,[6] was far more equivocal than Plaintiff implies: "I voted no, but it's a no with a lot of explanations. And I agree that the committee seems to be closer than perhaps appears … I wouldn't be upset if it were approved [by the FDA] with a lot of explanation." *Id*. at 351-52. This ambivalence even among those who voted "no" underscores that the negative vote resulted from different people evaluating the same data and reaching different judgments, not from previously undisclosed negative facts that contradicted Defendants' public statements. *See,*

[6] Many of the "reasons" that Plaintiff repeats to claim falsity are variations on the allegation that "Phase 3 trials *showed significant, potentially serious and life-threatening adverse effects* of the type that scuttled approval for other obesity drugs, including…." *E.g.*, ¶¶ 57(a)-(e). This allegation takes great liberties with the record. What Dr. Burman actually said, in weighing against the clear efficacy of Qnexa is: "On the other hand, the medication has serious *potential* adverse effects, including.… Some of these side effects are serious and could be life threatening, and they have to be weighed against" the drug's positive factors. Ex. G at 352 (emphasis added). In other words, these were "*potential*" issues, not side effects that had been "show[n]."

e.g., *Padnes*, 1996 WL 539711, at *5; *see also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1225 (S.D. Cal. 2001) ("Although Plaintiffs may have established a legitimate difference of opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim.").

a. Defendants' statements about Qnexa's safety were accurate in the context of the known safety profiles of Qnexa's component drugs.

Plaintiff's attempt to work backward from the Committee vote fails for another reason: the millions of patient years of experience with Qnexa's component drugs, phentermine and topiramate, provided a context for, and confirmed the accuracy of, Defendants' statements about Qnexa's safety. This basic fact was explicitly noted in VIVUS's public disclosures throughout the class period (and long before). *E.g.*, Exs. P at 37 & Q at 64. It is also clearly stated in the Committee briefing materials. *See* Ex. D at 154 ("The safety and tolerability profile of QNEXA *should be evaluated in the context of the known adverse effects of the component agents* when used as monotherapy for various indications."); Ex. J at 3 ("*Based on the individual safety profiles of phentermine and topiramate*, the safety assessment of PHEN/TPM includes, but is not limited to, five areas of particular interest….") (emphasis added).

Plaintiff repeats Dr. Burman's list of *potential* side effects of Qnexa after nearly every quoted statement, but the trial data did not show these hypothetically possible issues to anything more than that (Plaintiff's mischaracterization (*see* n.6) notwithstanding). Instead, the stated concerns were based on known issues about the *component drugs*, typically administered at much higher doses than in Qnexa. This led some members to want longer-term data to rule out potential adverse effects, but all potential issues were publicly known. The prescribing information for Adipex-P (phentermine) and Topamax (topiramate), appended to VIVUS's briefing document, lists each potential adverse effect that gave Dr. Burman hesitation, and covers all five areas of interest identified by the FDA.[7] In the context of the known, well-defined

[7] *See* Adipex-P prescribing information, Ex. D at 171-74 (noting risks of tachycardia and palpitations, dizziness and insomnia, and listing fetal harm or adverse impact on reproductive capacity as unknowns); Topamax prescribing information, *id* at 175-236 (discussing safety issues at length, and warning about suicidal behavior and ideation, metabolic acidosis, cognitive/ neuropsychiatric reactions, and serious adverse fetal effects). *See also* Ex. P at 37. In this context, Plaintiff's insinuations about the "potential life-threatening adverse effect" of Qnexa ring hollow, particularly in the absence of trial data showing realization of this purported potential.

profiles of Qnexa's components, Defendants' statements were accurate.

Beyond statements specific to certain side-effects, which we address below, Plaintiff repeatedly quotes Defendants' statements that Qnexa's Phase 3 safety results presented "no issues of concern at this point" or "no surprises." *See, e.g.*, ¶¶ 57(e), 86(f), 96(c), 126(h). Again, these statements came in the context of the components' known safety profiles, as the quoted statements clearly reflect. *See, e.g.*, ¶ 70 ("[N]othing in here of concern *that we haven't seen in other trials or is not in the label of existing studies*.") (emphasis added); Ex. K at 4 ("[T]he side effects we saw were expected. These were side effects that are consistent with either weight loss or consistent with the two components."); ¶ 150 ("Nothing that was unusual, nothing that was exacerbated by the combination. So, again, that's the benefit of using drugs that have been approved and used before. There are no surprises and that's really the message here."). Defendants' point was that Qnexa's Phase 3 trials did not present unexpected and/or *previously unknown* safety issues as a result of the drugs' combination.

Unable to dredge up anything in either the data itself or in the comments of Committee members to challenge VIVUS's stated belief on the consistency of Qnexa's safety profile with that of its components, Plaintiff simply invents a "reason" the statements are misleading, alleging:

> although combination therapy can enhance the safety and/or effectiveness of two drugs, the data from the Phase 3 Trials *showed* significant, potentially serious and life-threatening adverse effects including *potential* teratogenicity, increased suicidal ideation, cognitive issues, decreased bicarb, tachycardia, and possible renal stones, *which meant that the combination of topiramate and phentermine was increasing the risks and magnitude of the side effects found in the individual constituent compounds and/or creating new side effects not seen in the individual compounds*, which is the effect of combining two drugs that should not be combined.

See ¶¶ 106(g), 126(e)(iv) & (g)(iv), 167(c), 174(c), 179(b)(iii) (emphasis added). As noted, the first clause of this mantra represents a simple twisting of the record – Committee members stated these side effects were *potential*, not *show[n]*. *See supra* n.6. More troubling is the second clause, beginning "which meant…." In this clause, Plaintiff does not even bother distorting the record; he simply makes it up without *any* reference to the data, Committee member comments, analyst statements, or any other purported factual underpinning. Plaintiff cites no fact to support his assertion that Qnexa "increas[ed] the risk and magnitude" of side effects known to its

component drugs or "creat[ed] new side effects not seen in the individual compounds" – because no such facts exist. Plaintiff cannot show VIVUS's statements to be false and misleading by contradicting them with made-up "reasons" that have no grounding in fact, and repeating his invention over and over does not cure this defect.

b. Defendants' statements about trial results related to specific potential side effects were not false or misleading.

Even if the safety data reviewed by the Advisory Committee had only become public for the first time on July 15, 2010 (rather than two days earlier), the data were consistent with, not contradictory to, VIVUS's public statements. VIVUS's decision to focus on moderate and severe adverse events in reporting initial, top-line results is not rendered misleading by a later data release showing additional, less-severe events, as this Court has repeatedly held, including in two recent cases dismissing Section 10(b) claims. *See In re Rigel Pharm., Inc. Sec. Litig*, No. 09-00546 (N.D. Cal. Aug. 24, 2010) Order Granting Motion to Dismiss Plaintiff's Consolidated Amended Complaint ("*Rigel* Order") (White, J); *Philco Invs. LTD v. Martin*, 2011 WL 500694 (N.D. Cal. Feb. 9, 2011) (Breyer, J); *accord Philco*, 2011 WL 4595247 (N.D. Cal. Oct. 4, 2011).

In *Rigel*, the Court held:

> Defendants stated they were providing the 'key safety results,' and did not imply that they were disclosing, at that time, all adverse incidents. The fact that Defendants later disclosed more detailed results, *including incidents of lesser severity*, does not render their earlier statements false or misleading.

Rigel Order at 15 (emphasis added), *citing Padnes*, 1996 WL 5389711, at *5 ("Defendants, like any other company wishing to publicly discuss the results of a scientific study, had to make a judgment as to which specific bits of information about the study and its conclusions to disclose."). Likewise, in *Philco*, the Court found that public statements concerning top-line results of a Phase 2 study were not misleading because they did not initially disclose all material adverse results even when more details were released later. 2011 WL 500694, at *8 ("Though the release did not contain all of the detail Plaintiffs would have liked, it was not misleading."), *citing Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1007 (9th Cir. 2002). VIVUS repeatedly explained that it was providing summary information from the trials. *See, e.g.*, ¶ 125; Ex. C at 8. It was equally clear when it provided data related to moderate and severe (rather than *all*) adverse

events. *See, e.g.*, ¶ 55(e) ("Depression or depressed mood adverse events *of a moderate to severe nature* were less than 2% and were similar among patients in the Qnexa and placebo groups"); ¶ 110 ("there was no difference between Qnexa and placebo for incidence of *moderate or severe* depression/depressed mood (1.7%, 1.7%, 1.2% and 1.9% for placebo, Qnexa low-dose, Qnexa mid-dose and Qnexa full-dose, respectively")). As *Rigel* and *Philco* hold, these statements do not constitute a Section 10(b) violation, or facts of a sort that could support one.

Doubtless, Plaintiff's contrary argument will again focus on the Supreme Court's decision in *Matrixx Initiatives, Inc. v. Siracusano*, which held that adverse events that are not statistically significant may need to be disclosed in some circumstances. 131 S. Ct. 1309 (2011). But *Matrixx* explicitly says that the relevant standard "does not mean that pharmaceutical manufacturers must disclose all reports of adverse events" as that would "bury the shareholders in an avalanche of trivial information." *Id*. at 1318, 1321. Yet the New Complaint makes clear that this is precisely what Plaintiff would have obliged VIVUS to do. By requiring disclosure of every adverse event – for example, calling for additional data on mild events despite prior disclosure of moderate and severe events – Plaintiff's hindsight-driven view is essentially that nothing short of disclosure of every shred of available data could preclude a securities claim where there is a later adverse FDA or panel decision. That is not what *Matrixx* held. As this Court has recently noted, "[I]t is not sufficient for Plaintiff to allege that statements are merely incomplete," as "[n]o matter how detailed and accurate disclosure statements are, there are likely to be additional details that could have been disclosed but were not." *See Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.* 2011 WL 3501733, at *11 (N.D. Cal. Aug. 10, 2011) (Koh, J). *See also Philco*, 2011 WL 4595247, *7 n.11. For all its increased size, Plaintiff's New Complaint still fails to identify any statements that were knowingly false or misleading when made.

In an attempt to give Plaintiff's pleading the structure he has opted not to provide himself, Defendants previously broke his scattershot claims into the five specific areas that the FDA focused on at the Advisory Committee meeting (psychiatric, cognitive, cardiovascular, acidosis, teratogenetic) and discussed those allegations at length. Prior Motion at 14-21; Prior Reply at 9-14. In many more pages, the New Complaint makes the same side-effect allegations as before.

We respectfully refer the Court to our prior papers and will provide here only an overview response to each category to remind the Court of Plaintiff's primary claims and their deficiencies.

Psychiatric Results. In response to *any* VIVUS statement that touches on psychiatric safety, suicidality, depression, (*see, e.g.*, ¶¶ 55(c)-(e)) or even general safety and tolerability of Qnexa (*e.g.* 55(f), (g), 57(a), (b)), Plaintiff trots out the same selected assertions from the much-later FDA Memo, comments of Advisory Committee members, and/or the meeting's summary minutes. He generally asserts that Defendant statements misled because: (1) there were more total psychiatric adverse events for patients taking Qnexa than those on placebo; (2) more patients on Qnexa (especially at high dose) discontinued the study because of adverse events (including psychiatric events) than those on placebo; and (3) longer-term and/or additional studies would be needed to determine whether Qnexa users (including those on other medications or suffering from other conditions) in fact experienced psychiatric side effects (including depression or suicidal ideation). *See, e.g.*, 55(c)(i)-(vii). These allegations do not show Defendants' statements were misleading. Even the Committee members and FDA analysts on which Plaintiff relies note that there was no signal for suicidality (*see, e.g.* Dr. Rogawski at ¶ 228) or depression (¶ 253)) from Qnexa use based on the data *actually collected*. Furthermore:

- VIVUS disclosed Phase 3 trial data on *moderate and severe* depression on the first day of the class period. Ex. L at slide 30. That there were more *total* adverse events (the vast majority being *mild*), in the Qnexa arm versus placebo, does not undermine or change what VIVUS reported. *See Rigel*, Order at 15; *Philco*, 2011 WL 500694, at *8.
- VIVUS also disclosed data showing psychiatric adverse event-related discontinuations on the first day of the class period. *See* Ex. L at slide 29 (comparing discontinuation rates between placebo and top-dose Qnexa for insomnia (0.4% to 1.7%) depression (0.2% to 1.4%), and anxiety (0.3% to 1.1%)). Plaintiff does not explain how later confirmation of these numbers makes Defendants' earlier statements misleading. *Id.*
- The labels of both phentermine and topiramate include extensive warnings of possible psychiatric side effects (*e.g.*, Ex. D at 172-73, 181-82), and VIVUS disclosed the risk that these effects, as well as the shadow cast by adverse effects of other weight-loss drugs, could negatively affect Qnexa's approval chances (*e.g.*, Ex. P at 36-39, 43); and
- VIVUS's stock price *rose* following public release of complete data on psychiatric side effects, (Ex. H; *see also* Ex. F at ¶ 3 (noting Qnexa may cause "a 'low' level of psychiatric side effects," citing the FDA Memo)).

These judicially noticeable *facts* point up the insufficiency (and absurdity) of these allegations.

Cognitive Results. The same analysis applies to the complained-of statements about

cognitive effects. Plaintiff asserts that Defendant's statements that Qnexa's Phase 3 trial results showed no clinically significant change in overall cognitive function or effect on psychomotor skills were false or misleading because: (1) "patients taking Qnexa had a 4 times higher risk of cognitive impairment" *(e.g.*, ¶¶ 57(a)-(e)), (2) "discontinuations due to cognitive-related adverse effects occurred more frequently in Qnexa-treated subjects than subjects who received the placebo" (*e.g.*, ¶¶ 55(g)-(h), 59(d)-(e)), and (3) "Qnexa produced statistically significant and clinically relevant negative effects on cognitive function" (*e.g.*, ¶¶ 55(f), 60(b), 61(b)).

As with the psychiatric data, VIVUS disclosed that "[m]ost cognitive-related AEs were mild or moderate in severity." Ex. D at 147; *see also* Ex. G at 73 (90% of neuropsychiatric adverse events (cognitive and psychiatric events together) were mild or moderate). The FDA Memo notes that "[t]he clinical significance of these imbalances [between adverse event levels] is unknown." Ex. J at 5.[8] And again, VIVUS disclosed the cognitive-related discontinuations in an October 29, 2009 press release (referenced at ¶ 102). *See* Ex. M. The cognitive-effects data were not surprising when released given topiramate's known cognitive side-effect profile, and were not a surprise at the Committee meeting either. ¶ 235 and Ex. N ("The majority of the panel was not concerned with [cognitive] issues.… The adverse events *were not unexpected and fell within as per* [sic] *the Topamax label*.").[9]

Cardiovascular Results. As in the Prior Complaint, Plaintiff asserts a litany of allegedly hidden cardiovascular issues to try to contradict Defendants' positive statements about Qnexa's positive effect on cardiovascular *risk factors and co-morbidities* (which, as the secondary

[8] Even in its detailed briefing FDA document, VIVUS maintained that "no clinically meaningful effects on cognitive function … were observed over 1 year." Ex. D at 121.

[9] The October 29 press release reviewed results of the Repeatable Battery for the Assessment of Neuropsychological Status, or RBANS, administered during Qnexa clinical studies, noting that Dr. Christopher Randolph, an expert in cognitive function who developed RBANS, had reviewed the results and found: "Qnexa at the doses tested does not appear to produce a clinically significant change in cognitive function in this patient population." Ex. M at 2. Plaintiff ignores this and instead focuses on later comments in the FDA Memo, which states, "[t]he RBANS study demonstrated that *topiramate*, given either alone or in combination with phentermine, produced statistically significant and clinically relevant negative effects on cognitive function, as assessed by Total Index scores." Ex. J at 50 (emphasis added). But VIVUS's statements about its cognitive data's clinical relevance are not rendered false or misleading because the FDA's later assessment differed from that of another expert – indeed, the tool's creator.

endpoint of the Phase 3 trials, was an *efficacy*, not a *safety*, consideration). *Compare, e.g.*, SAC ¶¶ 55(a), 103(d), 118(a), 149 *with* AC ¶¶ 46, 82, 99, 112. The FDA and the Committee unequivocally confirmed those efficacy statements: "PHEN/TPM-treated groups had the expected improvements in blood pressure, lipids, and glycemia." Ex. J at 3. Qnexa's efficacy, *including* its positive impact on cardiovascular risk factors, has not been challenged.

As for *safety*, Plaintiff again claims that VIVUS's assertions about cardiovascular (and other) side effects of Qnexa are false because: (1) "patients taking Qnexa reported an increased heart rate"; (2) "there was *potential* for cardiovascular risks, including tachycardia, arrhythmias, stunned myocardium, cardiomyopathy, and congestive heart failure … stroke and intracerebral hemorrhage"; and (3) "during the Phase 1 [Thorough QT ("TQT")] Trial a depletion of potassium in patients was noticed" and patients "were provided with an increase in potassium…to mask the potential cardiovascular risk." ¶¶ 55(a), 57(a)-(e) (emphasis added). None of these "reasons" substantiates Plaintiff's claims. The first parrots a fact disclosed in the first days of the class period; Plaintiff again only disputes VIVUS's interpretation of the data. The second is not a fact, but a greatest-hits collection of every possible cardiovascular-related concern expressed by anyone on the Advisory Committee, a few of which were noted in support of some calls for longer-term studies. *See* Ex. G at 189, 316, 320, 323. The third is an irrelevant red herring.

Plaintiff points to Dr. Day's September 11, 2009 statement that "there is no cardiovascular signal to speak of" because, given the measured drop in blood pressure, a "one beat per minute increase has no statistical or clinical significance" and was of no concern (¶ 76(d) and (e)). But Plaintiff offers no facts challenging the data VIVUS presented to the Committee indicating that Qnexa trial patients experienced an average of 0.6-1.6 beats per minute increase in heart rate across treatment groups as compared with placebo. Ex. D at 15.[10] He only challenges, with hindsight, Dr. Day's conclusion.[11] The Committee members – even those Plaintiff uses as

[10] Plaintiff also notes Mr. Wilson's statement that FDA had told VIVUS that there was no need for an outcome study for cardiovascular risk for the treatment of obesity (but noting that FDA could change its mind at any time) (¶ 127). But Plaintiff alleges no facts to suggest that Mr. Wilson misrepresented VIVUS's communications with the FDA as of the time he spoke.

[11] The conclusion that the slight increase in average heart rate was neutralized by a corresponding decrease in blood pressure was reached with knowledge of, and applied equally to, a small

sources for his list of *potential* concerns – did not attack VIVUS's results; at most, some expressed a desire for data from longer studies. *See, e.g.*, ¶ 223 (Dr. Thomas calling for a cardiovascular trial focused on a higher-risk group); ¶ 228 (Dr. Rogawski (who voted to approve) noting need for more data on risk of stroke). The Committee's suggestion for further study does not suggest that VIVUS's statements about cardiovascular safety were misleading, especially where: (1) Qnexa showed no adverse effects beyond those identified on the label for phentermine – which notes risk of cardiovascular side effects, yet has been prescribed to millions annually for a half-century – and (2) VIVUS had already announced, before the July 15 meeting, a comprehensive outcomes study of cardiovascular effects, with a five-year average treatment duration. Ex. D at 17-18.

Plaintiff's opaque allegations about potassium in the Phase 1 TQT trial are addressed in our scienter discussion below. *See infra* Section IV.C.1. However, it is worth noting that:

- Plaintiff cites no VIVUS statement about the TQT trial; there was no mention of the TQT trial in either the FDA Memo or at the Committee meeting;
- decreased potassium (hypokalemia) is listed as a potential side effect on the Topamax label (as Plaintiff notes at ¶ 263) so it was unsurprising in VIVUS briefing documents, which disclosed hypokalemia in 0.4%, 0.4%, 1.4%, and 2.5% of patients across treatment classes, Ex. D at 105; and
- Plaintiff never explains how *potassium results* for 112 patients in the *Phase 1* TQT trial affect or translate into *cardiovascular results* for 4500 patients in the *Phase 3* trials, when the latter were separately tested and independently analyzed.

The potassium allegations cannot support an inference that VIVUS's statements about cardiovascular results, or safety in general, were false or misleading.

Teratogenicity and Metabolic Acidosis Results. As in the Prior Complaint, Plaintiff fails to complain about *any* statement – contradicting the Committee findings or otherwise – from Defendants on either topic. Yet he claims that VIVUS's failure to disclose that Qnexa would likely receive a Pregnancy Category X label and had the *potential*, like topiramate, for decreased bicarbonate levels rendered fraudulent its statements about Qnexa safety. *E.g.*, ¶¶ 57(b), 62(b), 116(k). But VIVUS's disclosures, in parts that Plaintiff ignores, demonstrate that VIVUS

number of outlier patients whose heart rates increased by as much as 20 beats per minute (although these individuals had a low baseline rate). Ex. G at 55-58. While Plaintiff notes the outliers, *e.g.*, ¶ 55(a)(ii), he alleges no facts to contradict the conclusion._

disclosed the very risks Plaintiff alleges were kept secret.

For example, VIVUS's Forms 10-Q filed November 4, 2009 and May 7, 2010, and its Form 10-K filed March 10, 2010 disclose that, while no pregnancy risks were observed during the trials, *if approved, Qnexa labeling would warn against use by women who are pregnant or may become pregnant*. Exs. O at 62, P at 38, Q at 65; *see also* Ex. C at 10 ("[T]his is not a medicine that should be used in women that want to get pregnant, and if they become pregnant, they should stop taking [it] immediately. So you're going to see that in our labeling."). Potential risks of metabolic acidosis, a known side effect of topiramate, were also disclosed in those same filings. Exs. O at 62; P at 37; Q at 64; *see also* Ex. D at 182-84 (Topamax label warnings). By no stretch can Plaintiff's allegations related to these two areas support a securities claim.

2. Statements of General Optimism Are Not Actionable

Plaintiff also complains about other comments broadly touting Qnexa's safety profile and expressing enthusiasm about both Qnexa's trial results and future prospects. Again, accurate statements about Qnexa's safety and tolerability were made and understood in the context of the known characteristics of its components. As we discuss in Section IV.B.3 below, VIVUS's comments about potential FDA approval and/or commercial success were forward-looking and accompanied by meaningful cautionary language, and so not actionable. What remains are general statements of opinion and optimism – statements that cannot support a securities fraud claim. *E.g.*, *In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 868 (N.D. Cal. 2004); *In re Netflix, Inc. Sec. Litig.*, 2005 WL 1562858, at *7 (N.D. Cal. June 28, 2005).

Claims that Qnexa has an "excellent" or "compelling" risk/benefit profile (*e.g.* ¶¶ 57(a), 69(b), 86(c)), or that the studies have shown "remarkable" safety and efficacy (¶¶ 57(d), 63), are not actionable under Section 10(b).

> It is well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true, or constitute puffery or ordinary expressions of corporate optimism.… Likewise, statements of opinion are insufficient to form the basis of a misrepresentation or omission complaint under § 10(b).

In re Bristol Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (citations omitted); *accord Wenger*, 2 F. Supp. 2d at 1245. In *Bristol-Myers*, statements that a drug was "a

tremendous strategic opportunity," had "real blockbuster potential," had "potential to be one of the most exciting, if not the most exciting" cancer drugs and was "a first-in-class novel blockbuster drug for treating cancer" all were held to be non-actionable. 312 F. Supp. 2d at 557-59. The same result should obtain here. *See also Philco*, 2011 WL 500694, at *6; *In re VeriFone Sec. Litig.*, 784 F. Supp. 1471, 1481 (N.D. Cal. 1992).

Nor can optimistic statements about prospects for FDA approval, commercial success and partnership and marketing opportunities support fraud claims where Defendants repeatedly qualified them. *See, e.g.* ¶ 56 ("Based on the efficacy and safety data that you will see, *we believe* Qnexa meets all FDA requirements for approval."); ¶ 85 ("*[W]e believe* we have or Qnexa has a very compelling benefit risk profile, which *we believe* will support approval, reimbursement, and ultimately commercial success."); ¶ 104 ("*[w]e believe* the overall efficacy and safety profile of Qnexa supports approvability."); *see also other beliefs cited in* ¶ 54 ("compelling [partnership] opportunity"), ¶ 122 (data supports "both approval as well as reimbursement") & ¶ 129 (PDUFA data "justifies approval"). As discussed below in the scienter context, Plaintiff offers no facts suggesting that Defendants did not genuinely and reasonably hold these beliefs, and this alone dooms any claim based on them. *See infra* Section IV.C. More generally, these optimistic assertions are not actionable, as "[t]he securities laws neither require corporate officers to adopt a crabbed, defeatist view of the company's business prospects nor permit dissatisfied shareholders to assert serious allegations of fraud based on the perfect hindsight afforded by the passage of time." *In re Sierra Wireless, Inc. Sec. Litig.*, 482 F. Supp. 2d 365, 367 (S.D.N.Y 2007); *see also In re Pfizer Sec. Litig.*, 538 F. Supp. 2d 621, 631 (S.D.N.Y. 2008) ("corporate officials need not present an overly gloomy or cautious picture" about a new drug's potential so long as public statements are consistent with reasonably available data) (internal citations omitted); *Yourish v. California Amplifier*, 191 F.3d 983, 997 (9th Cir. 1999) ("[I]t is clearly insufficient for plaintiffs to say that [a] later, sobering revelation[] make[s] [an] earlier, cheerier statement a falsehood.")

3. Defendants' Risk Disclosures Undercut Plaintiff's Claims

VIVUS qualified and tempered its stated optimism in another critical way: it was candid about the risks it faced in getting Qnexa approved and marketed. *See E.g.*, Exs. O, P, Q, S, T.

These extensive disclosures are significant for two reasons. First, they constitute the cautionary language that renders Plaintiff's claims based on forward-looking statements non-actionable. Second, they dispel Plaintiff's implication that the issues raised by the Advisory Committee and the possibility of its negative vote were hidden from investors; in fact, the opposite is true.

Defendants' comments about Qnexa's prospects were forward-looking statements protected under the PSLRA safe harbor. 15 U.S.C. § 78u-5(i)(1)(B); *see also Noble Asset Mgmt. v. Allos Therapeutics*, 2005 WL 4161977, at *9 (D. Colo. Oct. 20, 2005) (statements about FDA approval prospects not actionable). Each VIVUS press release cited by Plaintiff included warnings about the uncertainties of forward-looking statements, and additionally referred investors to VIVUS's SEC filings,[12] which in turn were chock full of risk factors, including page after page devoted to the very risks Plaintiff says were hidden – potential difficulties with FDA approval; the side-effect profiles of Qnexa's components and possible resulting labeling restrictions for Qnexa; the possibility of FDA requiring additional, expensive trials; concerns about Qnexa's association with Fen-Phen; and many more hazards.[13] The risks referenced in these warnings include those risks that resolved negatively on July 15, 2010. In response to these cautions about the uncertain future, Plaintiff offers the boilerplate that "[t]o the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ" from those statements. ¶ 307. The public record reflects otherwise. VIVUS's disclosures render Defendants' statements non-

[12] Each VIVUS press release included a warning akin to this one issued September 9, 2009, the first day of the alleged class period (Ex. B at 4, emphasis added):

> Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 … These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, … *risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations.…There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful* … Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2008 and periodic reports filed with the Securities and Exchange Commission."

[13] *See, e.g.*, VIVUS's 2009 10-K (Ex. P), Section 1A, at 31-78 (*48 pages* of risk factors).

actionable as a matter of law under the PSLRA safe harbor and the bespeaks caution doctrine. *See In re Bare Escentuals, Inc. Sec. Litig.*, 745 F. Supp. 2d 1052, 1080 (N.D. Cal. 2010).

Plaintiff tries to explain away these cautions and avoid their impact on his claims with a new section of his pleading. ¶¶ 184-203. VIVUS's disclosures offer no shelter, Plaintiff says, because (a) they were made when Defendants knew the various "facts" that he derives from the (later) FDA Memo or Committee member comments (*e.g.*, ¶¶ 189, 192, 195) and (b) in the case of FDA approval risks, the disclosures were "nullified" by Defendants' stated confidence in Qnexa and opinion that it was "remarkably" safe and would be approved (¶¶ 190, 193). Both assertions fail. The claim that the disclosures contradicted known, but supposedly undisclosed, results of the Phase 3 trials is undermined by Plaintiff's failure to identify what those purportedly known-but-undisclosed results were. As for the nullification-through-confidence theory, the law is clear that legitimate optimism does not constitute securities fraud. *See supra* Section IV.B.2.

C. Plaintiff Fails to Allege A Strong Inference of Scienter

Plaintiff's failure to adequately plead scienter also compels dismissal of the New Complaint. Plaintiff has made no substantial change to his scienter allegations. *Compare* SAC ¶¶ 242-96 *with* AC ¶¶ 148-89. As Defendants argued in their Prior Motion, Plaintiff comes nowhere close to meeting the very high scienter pleading standard. To state a securities fraud claim, Plaintiff must allege with particularity facts giving rise to a "strong inference" that Defendants engaged in conscious or deliberately reckless misconduct. *Silicon Graphics*, 183 F.3d at 974; 15 U.S.C. § 78u-4(b)(2). Those specific alleged facts must create a "cogent and compelling inference" that Defendants analyzed the results of the Phase 3 trials and concluded they threatened the prospects for approval and commercial viability of Qnexa. *See Pfizer*, 538 F. Supp. 2d at 631-32. The Court must also consider plausible non-culpable explanations for Defendants' conduct. *Tellabs*, 551 U.S. at 324.

Rather than accept the reasonable (and true) story that VIVUS was legitimately excited about Qnexa Phase 3 trial results – results that without dispute showed efficacy at or beyond FDA approval benchmarks[14] and a safety profile consistent with Qnexa's long-approved component

[14] Ex. J at 3 ("Per the efficacy criteria outlined in the Division's 2007 draft guidance, all three

drugs – Plaintiff contends that VIVUS's expressed enthusiasm and confidence were phony. But he pleads no specific facts that make his the more compelling or cogent story. Nor does he explain why Defendants poured millions of dollars into clinical trials for an approval process they purportedly knew was doomed. *See In re Apple Computer Inc., Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (inference of bad faith dispelled by defendants' conduct staking the company's future on ongoing efforts). Indeed, nothing in Plaintiff's allegations contradicts the far-more-plausible, non-culpable explanation that Defendants reasonably believed in Qnexa's results, prospects for approval, and potential marketability. *AstraZeneca* is instructive:

> The cases recognize that, particularly in the testing and development stage, the possible beneficial effects of a drug may be accompanied by adverse side effects, and there may be uncertainty as to how the risk-benefit balance ultimately turns out, and how it will be viewed by regulators. But if the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud, even though at a later point some event occurs which prevents the marketing of the drug or makes it necessary to take the drug off the market.

559 F. Supp. 2d at 470, *citing In re Carter-Wallace Sec. Litig.*, 220 F.3d 36 (2d Cir. 2000).

At most, Plaintiff alleges that Defendants were aware, at some unspecified time, that Qnexa, like virtually every drug, might have some side effects. But that allegation is hardly remarkable and falls well short of asserting facts that Defendants actually concluded that Qnexa was unlikely to be approved or marketable. In *Pfizer*, the court noted that the "ultimate failure [of an NDA] is not evidence that the side effects were thought to be unmanageable at the time the alleged misstatements were made. Fraud-by-hindsight is not sufficient to establish liability under Rule 10b-5." 538 F. Supp. 2d at 634. The same is true here; scienter is insufficiently pled.

1. The Confidential Witness Allegations Are Unchanged and Add Nothing

Plaintiff attempts to allege scienter with the same assertions attributed to the apparently same unidentified Confidential Witnesses ("CWs") as in the Prior Complaint. But as Defendants noted in the Prior Motion, these vague allegations say nothing about, for example, *what* information discounted VIVUS's statements about Qnexa, *when* that information was allegedly

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doses of PHEN/TPM were efficacious for weight loss."); Dr. Burman, Ex. G at 352 ("Qnexa does meet or exceed the agency's requirement for efficacy; I don't think there's any issue there.")

known, *who* knew it, and most importantly, *how* it contradicted public statements. The CW assertions do not offer "cogent and compelling" support for Plaintiff's claims.

To begin, Plaintiff's allegations do not support an inference that his CWs would even know information about these critical points. Five of the six CWs are not alleged to have had *any* connection to Qnexa, but are instead said to be sales representatives for VIVUS's one marketed (erectile-dysfunction) drug (CW3-CW6) or a "scientist" in its New Jersey manufacturing facility alleged to have left VIVUS before the Qnexa Phase 3 trials concluded (CW2). *See* ¶¶ 247-48. In short, Plaintiff fails to allege facts establishing his CWs as reliable sources. *See Applestein v. Medivation, Inc.*, 2011 WL 3651149, *5 (N.D. Cal. Aug. 18, 2011) (adequate basis for CW reliability depends on CW's position in the company).

Even assuming the CWs' competence, the allegations add little. Plaintiff fails to identify any actual contradictory information through his CWs, using them only to assert that there were "concerns" or "discussions" about potential safety issues – *see, e.g.*, ¶ 253 ("constant discussion" about various health issues) – a fact, if fact it be, that again is unremarkable as one would expect that people promoting Qnexa's candidacy would focus in part on safety. Plaintiff does not describe what was actually said, much less where, when, or by whom – all basic requirements for pleading fraud. *E.g. Ronconi*, 253 F.3d at 429.[15] Nor does Plaintiff explain how any concerns mentioned in the CW allegations conflicted with VIVUS's contemporaneous public statements. *See In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 351-52 (S.D.N.Y. 2011) (CW allegations that bank managers received reports "detailing significant and widespread problems" with the bank's lending insufficient where they "fail to specify which reports revealed the widespread lending problems, what information those reports contained, and whether the reports contradicted" defendants' public statements); *see also Autodesk*, 132 F. Supp. 2d at 844.

As discussed in prior briefing, almost none of the CW allegations actually links defendants Wilson or Day to the "constant discussion" of health issues. Rather, the CWs refer to

[15] Nor do allegations that "company representatives" told the *sales* staff (for a different drug) that *if* there was a problem with cardiac issues, they would need to revise Qnexa's labeling (¶ 256), or that "everyone, including senior management, knew the drug had potential for [suicidality and heart problems]" (¶ 257) advance Plaintiff's position. Beyond being far too vague, VIVUS disclosed these possibilities; Qnexa's components had the same issues. *See supra* Section IV.B.3.

themselves and Plaintiff seeks to bring in the Defendants by implication. *See* ¶¶ 253-55 ("[CW2] and others" discussed likely problems with Qnexa; "[CW4] was aware of and stated" risk of identified side effects with the Fen-Phen component of Qnexa). And in the rare case when Plaintiff alludes to Wilson or Day – through vague references that "senior management" "*should have been*" receiving progress reports on the trials (with no description of the alleged timing) – he asserts no information flow that contradicts the public statements. *See* ¶ 248. In fact, the one reference to Wilson's position on a particular safety matter notes his confidence, not pessimism: "Wilson, as well as other management, *thought Vivus could overcome* [any *potential* cardiac] problems because [Qnexa] could be labeled differently." ¶ 256 (emphasis added). This does not contradict the complained-of statements; it restates labeling considerations identified in, for example, the 2009 10-K. Ex. P at 35-38; *see also Pfizer*, 538 F. Supp. 2d at 634. Nor does the allegation state how the CW knew what Wilson (or "management") "thought," nor when they thought it (as compared with when presumably inconsistent public statements were made).[16]

The one CW allegation on which Plaintiff attempts to elaborate relates to the Phase 1 TQT trial. Again, the New Complaint does not allege any Defendant statement about that trial. But the allegation misses the mark regardless. *See* ¶¶ 262-68. Plaintiff again offers no specifics of what discussion took place, when or how the facts show that any Defendant statement was made with knowledge or reckless disregard of its alleged falsity. There is no corroboration, from other CWs or elsewhere, for CW1's alleged statements about supposed potassium issues in a Phase 1 trial; without more, those statements cannot support a fraud claim. *In re Daou Sys. Inc., Sec.*

[16] Again, *Wachovia*, 753 F. Supp. 2d at 352, is on all fours:

> [T]he majority of the CW allegations are either undated or pegged to an indefinite time period (*i.e.*, "after the acquisition")… This omission renders the task of matching CW allegations to contrary public statements all but impossible, since allegations about an unspecified time period cannot supply specific contradictory facts available to Defendants *at the time* of an alleged misstatement.… Such a pleading strategy effectively requires the Court to reconstruct the chronology of Class Period allegations in order to decipher what Defendants knew or should have known on the date of a particular statement. Because Rule 9(b) and the PSLRA contemplate heightened rather than debased pleading standards, the Court declines to find an inference of recklessness on the basis of the CW allegations.

See also Heywood, 2006 WL 5701625, at *5 (rejecting CW allegations containing only generalized, speculative statements).

Litig., 411 F.3d 1006, 1015 (9th Cir. 2005) ("adequate corroborating details" needed for CW statements).

At bottom, the CW allegations come nowhere near showing a management consensus that Qnexa's potential risks threatened its commercial viability, much less that any of Defendants' public statements were made with less than wholehearted and reasonable belief in their truth. *See Apple Computer*, 886 F.2d at 1113; *AstraZeneca*, 559 F. Supp. 2d at 471.

2. Defendant Wilson's Stock Sales, Made Pursuant To A 10b5-1 Plan, Cannot Support An Inference of Scienter, Much Less A Strong One

As for allegations of accepted indicia of scienter, Plaintiff attempts only one – insider stock sales. But Plaintiff's allegations of selling are inconsistent with his supposed fraud. ¶ 292. Plaintiff references some sales by Defendant Wilson, but acknowledges that they were pre-arranged, automatic sales under a 10b5-1 plan entered into *six months before the alleged class period*. ¶¶ 295-96. If anything, these sales "'rebut an inference of scienter.'" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 n.11 (9th Cir. 2008) (citation omitted). Moreover, because Mr. Wilson's 10b5-1 plan called for sales of 50,000-share tranches when the stock hit a pre-determined price, his sales were consistent with his general trading history. Exs. U (at 6), V, W (50,000-share trades in June and July 2009, pre-class period); *see Metzler*, 540 F.3d at 1066, *citing Silicon Graphics*, 183 F.3d at 986 (sales are suspicious only when "dramatically out of line with prior trading practices at times calculated to maximize" personal benefit). Plaintiff includes no allegations of stock sales by Defendant Day, again negating scienter. *E.g.*, *Borochoff v. GlaxoSmithKline PLC*, 2008 WL 2073421, at *8 (S.D.N.Y. May 9, 2008). The far more compelling inference to be drawn from the facts alleged – and those that are not – is that Defendants acted in good faith and without intent to deceive. *See Tellabs*, 551 U.S. at 324.[17]

3. Plaintiff's Other Mental State Allegations Are Also Insufficient

Plaintiff's other "motive and opportunity" scienter allegations – concerning the individual

[17] Plaintiff references stock sales of non-defendant Guy Marsh – which, like Mr. Wilson's, were pursuant to a 10b5-1 plan and in line with pre-class period trading – in an effort to skate past the *lack* of sales by Dr. Day. But even if Mr. Marsh's sales could somehow be seen as nefarious, "[m]isconduct by non-defendants cannot be used to allege defendants' scienter without adequate factual allegations that those defendants engaged in misconduct or knew that their disclosures were false." *Borochoff*, 2008 WL 2073421, at *8 (citations omitted).

defendants' incentive compensation, VIVUS's need for capital and the obvious importance of Qnexa's success (*see* ¶¶ 275-83) – prove nothing. The Ninth Circuit has made clear that allegations like these do nothing to distinguish the defendants from corporate executives generally. Accordingly, "[f]acts that establish a motive and opportunity … are not sufficient to create a strong inference of deliberate recklessness. In order to satisfy the heightened pleading requirement of the PSLRA for scienter, plaintiff 'must state specific facts indicating no less than a degree of recklessness that strongly suggests actual intent.'" *Twinde v. Threshold Pharm. Inc.*, 2008 WL 2740457, at *11 (N.D. Cal. Jul. 11, 2008), *citing Silicon Graphics*, 183 F.3d at 979; *see also Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.*, 2008 WL 2053733, at *7 (S.D. Cal. May 13, 2008) (interest in increasing performance-based compensation insufficient); *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002) (company's "alleged desires to obtain favorable financing" were "ordinary and appropriate corporate objectives" that do not create an inference of scienter). In short, Plaintiff's additional scienter allegations fail.

D. Plaintiff's Section 20 Claims Fail For Lack Of a Primary Violation

Plaintiff's claims under Sections 20(a) and 20(b) of the Exchange Act require a primary violation of that Act. Because he fails to plead a primary violation of Section 10(b), his claims under Section 20 fail as well. *Lipton*, 284 F.3d at 1035.

V. CONCLUSION

For the foregoing reasons, the New Complaint should be dismissed. Because Plaintiff has already had two opportunities to suitably amend his pleading and has shown an inability to do so, the dismissal should be with prejudice.

Dated: December 30, 2011

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